

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (previously cancelled)

Claim 2 (previously cancelled)

Claim 3 (previously cancelled)

Claim 4 (previously cancelled)

Claim 5 (presently amended): A method of arresting the flow of blood from a bleeding wound comprising the steps of:

- A. providing an effective amount of a substantially anhydrous compound of an a hydrophilic oxyacid salt combined with an effective amount of hydrophilic proton donor which will hydrate in the presence of blood to thereby promote clotting of the blood;
- B. applying said compound to the wound for a time sufficient to effect sufficient clotting of the blood to arrest substantial further blood flow from the wound.

Claim 6 (previously amended): The method of arresting the flow of blood as set forth in

Claim 5, wherein said oxyacid salt is taken from the group consisting of:

- alkali and alkaline salts;
- oxyacid salts of transition elements;
- halogen oxyacids; and
- alkali and alkaline oxides, peroxides and superoxides.

Claim 7 (currently amended): A hemostatic agent adapted to be applied directly onto a bleeding wound comprising:

an effective amount of an a hydrophilic oxyacid salt combined with an effective amount of a hydrophilic proton donor material, said oxyacid salt combining with blood to promote blood clotting at the wound, said hydrophilic proton donor material combining with, and thereby neutralizing, hydroxyl ions formed as said oxyacid salt combines with blood to effect clotting.

Claim 8 (previously amended): The hemostatic agent as set forth in Claim 7, wherein said oxyacid salt is taken from the group consisting of:

alkali and alkaline salts;
oxyacid salts of transition elements;
halogen oxyacids; and
alkali and alkaline oxides, peroxides and superoxides.

Claim 9 (previously amended): A hemostatic agent as set forth in Claim 7, wherein said hydrophilic proton donor includes:

a cation exchange resin;
an acid producing salt; and
an organic acid.

Claim 10 (previously amended) The hemostatic agent as set forth in Claim 7, further comprising:

a solid desiccant combined with said oxyacid salt and said hydrophilic proton donor material, said solid desiccant further accelerating blood clotting by absorbing water in the blood.

Claim 11 (currently amended): A hemostatic agent adapted to be applied directly onto a bleeding wound comprising:

an effective amount of ~~an~~ a hydrophilic oxyacid salt combined with an effective amount of a hydrophilic polymer material, said oxyacid salt combining with blood to promote blood clotting at the wound, said hydrophilic polymer material forming a protective cover over the wound.

Claim 12 (previously amended): The hemostatic agent as set forth in Claim 11, wherein said oxyacid salt is taken from the group consisting of:

alkali and alkaline salts;
oxyacid salts of transition elements;
halogen oxyacids; and
alkali and alkaline oxides, peroxides and superoxides.

Claim 13 (previously amended): The hemostatic agent as set forth in Claim 12, wherein said hydrophilic polymer material includes:

carboxy methylcellulose;
polyvinyl alcohol;
alginate;
a soluble gum.

REMARKS

The undersigned wishes to thank Examiner Choi for the courtesy of a telephone interview concerning the last office action and response thereto. During this telephone interview, clarification of the issues was achieved, particularly with respect to the appropriateness of and needed support for entering of the missing U.S. patent number co-invented by Patterson and Thompson. In further response to this issue, copies of the front pages of these only two (2) patents, 6,187,347 and 6,267,896 are included herewith.

Additionally, the hydrophilic nature of the claimed oxyacid salt was discussed and Examiner Choi urged submittal of support documentation for this aspect of this invention and further support for the notion that the elements described in the primary reference to Olson are all hydrophobic.

THE REJECTION

Claims 5 to 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Olson in view of Leveen, Burgeni, Eberl and Masci and further in view of Micelli. The teachings of Olson, Burgeni, Eberl and Masci were discussed by Examiner Choi in the previous office action, responded to in the amendment dated December 19, 2002, and were not discussed in detail in the present office action.

The newly added reference to Micelli teaches, according to Examiner Choi, that calcium chloride is effective in increasing the clotting effect of thrombin and that calcium chloride has notable coagulating action.

RESPONSE

Examiner Choi continues to assert the teachings of Olson for the combination of tantalum oxide and iron oxide for stoppage of bleeding of wounds and that this powder can be moistened with liquid agents. As previously argued by the undersigned, the

primary and important distinctive difference between the teaching of Olson and that of the present invention is that all of the elements and teaching of Olson surround the hydrophobic nature of the ingredients which, when wetted, form an inert, substantially chemically unchanged mixture which dries to form a protective cover over the wound which ultimately arrests bleeding. The present invention, contrarily, teaches a hydrophilic oxyacid salt combined with a hydrophilic proton donor material which, prior to administration onto a bleeding wound, must be substantially anhydrous and which, when applied to a bleeding wound, interacts with the water contained in the blood to effect a chemical reaction for the arresting of blood flow from the open wound.

Responsive to the previous office action, arguments were presented and accepted with respect to the hydrophobic nature of the tantalum oxide; however, inadvertently, little attention was given to the hydrophobic nature of iron oxide as taught by Olson. Regarding the issue of the hydrophobic nature of iron oxides, generally, these are not considered salts. In order to make a salt containing iron and oxygen, it first must be converted to an acid through one or more steps and then subsequently made into a salt. It is a difficult leap to assert that one of ordinary skill would have expected that salts of iron oxide would be effective in the stoppage of bleeding. Furthermore, Fe (II) oxide (FeO) and Fe (III) oxide Fe_2O_3 are both insoluble in water. See CRS Handbook of Chemistry and Physics at pages 4-65 and 4-66, copies enclosed, wherein iron (II) iron (III) oxide are clearly indicated to be insoluble (i) the hydrophilic oxyacid salt of the present invention are clearly hygroscopic, water soluble and strongly oxidizing to stop blood flow in a manner suggested in the present specification and is of a chemical rather than an inert mechanical nature. Moreover, in the Olson reference, column 4, lines 18 to 19,

Olson states that "Because the powder is nonreactive and will not go into solution in any of the body tissues...".

In summary, it has been shown that applicant is entitled to characterize the oxyacid salt claimed subject matter as being hydrophilic. It has also been shown that iron oxide is clearly hydrophobic as is tantalum oxide as previously argued and accepted. Finally, with respect to the teaching of Micelli and that calcium chloride is effective in increasing the clotting affect of thrombin, this aspect of the claimed invention being dependent under one or more of the independent claims as now amended in the case, it is submitted that this rejection is a moot issue.

COMMERCIAL SUCCESS AND LONGFELT NEED


Accompanying this response is an affidavit which was prepared and attested to by Douglas Goodman, the President of Biolife, LLC (formerly known as EcoSafe LLC), and the holder of all rights associated with this invention generally and including U.S. Patent 6,187,347. This affidavit, submitted under Rule 1.132, sets forth an outstanding, impressive and ever-growing portrait of commercial success of products embodying the invention and also reflects only a small portion of numerous unsolicited testimonials submitted to and/or prepared on behalf of Biolife LLC related to the successful use of products embodying the invention now marketed under one or more trademarks including **QR**. Those trademarks include **URGENTQR®**, **NOSEBLEED QR™**, **SPORTS QR™**, **FIRSTAID QR™** and **KIDS QR™**.

The commercial success outlined in the affidavit indicates a total sales of \$1.5 million which is ever growing based upon the yearly summary of sales in the affidavit. Moreover, the affidavit also sets forth numerous competitors in this marketplace which, had the present invention been obvious as suggested by Examiner Choi, would have

surely been motivated by this level of commercial success to have implemented marketing of a similar product. This commercial success has been achieved against a modest advertising budget of approximately \$120,000.

Based upon the foregoing arguments and affidavit of commercial success and the satisfying of a long-felt need in this market, it is submitted that this case and the claims contained herein as they now stand amended are in condition for allowance and same is respectfully requested. However, if there are any remaining issues, Examiner Choi is requested to contact the undersigned directly by telephone to resolve them.

Respectfully submitted,


Charles J. Prescott
Reg. No. 30,316
Charles J. Prescott, P.A.
2033 Wood Street, Suite 115
Sarasota, Florida 34237
(941) 957-4208

CERTIFICATE OF MAILING

I HEREBY CERTIFY that the foregoing is being deposited in the U.S. Mail, first class postage paid, addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, Virginia 22313-1450, this December 10, 2003.


Charles J. Prescott